UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AMGEN, INC. Plaintiff, v. SANDOZ INC., et al. Defendants.	Civil Action No. 18-11026 (MAS)(DEA) (Consolidated) *Document Electronically Filed*

DEFENDANTS' NOTICE PURSUANT TO 35 U.S.C. § 282

Defendants Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd, and Sandoz Inc., Alkem Laboratories Ltd., MSN Laboratories Private Ltd., Pharmascience Inc, and Zydus Pharmaceuticals (USA) Inc. (collectively "Defendants") submit this notice pursuant to 35 U.S.C. § 282 to plaintiff Amgen, Inc. regarding U.S. Patent Nos. 7,427,638 ("the '638 Patent"), 7,893,101 ("the '101 Patent"), 8,455,536 ("the '536 Patent"), 8,093,283 ("the '283 Patent), and 10,092,541 ("the '541 Patent").

Defendants hereby incorporate by reference all pleadings, contentions, expert reports, and previous communications that identify any patents or publications that Defendants cite to show that claims 3 and 6 of the '638 Patent, claim 6 of the '536 Patent, claims 1 and 15 of the '101 Patent, claims 2 and 27 of the '283 Patent, and claims 2, 19, and 21 of the '541 Patent are invalid for one or more of the reasons under 35 U.S.C. § 101, *et seq.* If any of the patents and publications identified below were not previously produced in discovery, this statement supplements Defendants' discovery responses, contentions, and expert reports under Federal Rule of Civil Procedure 26(e).

Defendants provide the list of patents and publications below to satisfy section 282 of Title 35 of the United States Code. The fact that Defendants list these patents, publications, and

other information does not reflect that all, more, or any number of these patents or publications will ultimately be used by Defendants in the presentation of evidence at trial. Defendants further incorporate by reference all information concerning the references set forth below presented in their invalidity contentions, expert reports, and other pleadings and submissions. Unless noted, all pages of the listed patents and references are being cited. Therefore, no implication should be taken that reliance on all of the identified patents and publications is necessary to support any of Defendants' patent invalidity defenses.

Defendants reserve the right to amend or supplement this statement as appropriate.

PATENTS

- U.S. Patent No. 8,629,173 (Issued Jan. 14, 2014 to Muller et al.)
- U.S. Patent No. 10,092,541 (Issued Oct. 9, 2018 to Day, et al.)
- U.S. Patent No. 6,962,940 (Issued Nov. 8, 2005 to Muller, et al.)
- U.S. Patent No. 7,208,516 (Issued Apr. 24, 2007 to Muller, et al.)
- U.S. Patent No. 7,427,638 (Issued Sep. 23, 2008 to Muller, et al.)
- U.S. Patent No. 7,659,302 (Issued Feb. 9, 2010 to Muller, et al.)
- U.S. Patent No. 7,893,101 (Issued Feb. 22, 2011 to Muller, et al.)
- U.S. Patent No. 8,455,536 (Issued Jun. 4, 2013 to Muller, et al.)
- U.S. Patent No. 8,802,717 (Issued Aug. 12, 2014 to Muller, et al.)
- U.S. Patent No. 9,018,243 (Issued Apr. 28, 2015 to Muller, et al.)
- U.S. Patent No. 9,724,330 (Issued Aug. 8, 2017 to Muller, et al.)
- U.S. Patent No. 9,872,854 (Issued Jan. 23, 2018 to Day, et al.)
- U.S. Patent No. 5,698,579 (Issued Dec. 16, 1997 to Muller, et al.)
- U.S. Patent No. 6,020,358 (Issued Feb. 1, 2000 to Muller, et al.)
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- European Patent Specification EP1752148 B1 (Published Jun. 23, 2007 to Man, et al.)

PUBLICATIONS

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- "Open-Label Study to Assess the Safety and Efficacy of Apremilast in Patients with Chronic Plaque Psoriasis Who Have Failed One Course of Biologic Therapy," Clinical Trial No. NCT01200264 Study Details (Sept. 13, 2010)

- "A Phase 2, Multi-center, Randomized, Double-blind, Placebo-controlled, Parallel-group Study Followed by an Active-Treatment Extension to Evaluate the Efficacy and Safety of Apremilast (CC-10004) in the Treatment of Behcet Disease," Clinical Trial No. NCT00866359 Study Details (March 20, 2009)

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- Apremilast Clinical Study Report CC-10004-PSA-001, A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Efficacy and Safety Study of Two Dose Regimens of CC-10004 in Subjects with Active Psoriatic Arthritis

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Defendants further discloses that Defendants do not intend to rely upon at trial any person who may be a prior inventor or may have prior knowledge of or may have previously used or offered for sale the invention of the patents-in-suit.

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Dated: May 14, 2021

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CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of May, 2021, I caused a true and correct copy of **DEFENDANTS' NOTICE PURSUANT TO 35 U.S.C. § 282** to be electronically filed with the Clerk of the United States District Court for the District of New Jersey and served upon all counsel of record via Electronic Case Filing (ECF).

Dated: May 14, 2021

By: *s/Theodora McCormick*
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